**IN THE UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF WEST VIRGINIA**

**WYETH,**

**Plaintiff,**

**v. // CIVIL ACTION NO. 1:07CV91**
**(Judge Keeley)**

**MYLAN PHARMACEUTICALS, INC.,**

**Defendant.**

**MEMORANDUM OPINION AND ORDER DENYING AND GRANTING CROSS MOTIONS FOR SUMMARY JUDGMENT [DKT. NOS. 160, 162 AND 178]**

Pending before the Court are the parties' cross motions for summary judgment. The plaintiff, Wyeth, seeks summary judgment as to whether the defendant, Mylan Pharmaceuticals, Inc.'s ("Mylan"), proposed production and marketing of a generic version of Effexor® XR will infringe on Wyeth's patents for that drug. Wyeth also seeks a judgment that its patents are not invalid for failure to name one or more inventors. Mylan seeks summary judgment as to whether Wyeth's patents are invalid for lack of enablement. For the reasons explained below, the Court **DENIES** Wyeth's motion regarding infringement (dkt. no. 160), **DENIES** Mylan's motion regarding enablement (dkt. no. 162), and **GRANTS** Wyeth's motion regarding inventorship (dkt. no. 178).

## I. FACTS AND PROCEDURAL HISTORY

In May 2007, Mylan filed an Abbreviated New Drug Application ("ANDA"), seeking approval from the United States Food and Drug

Administration ("FDA") to market a generic form of Effexor® XR, Wyeth's successful extended-release version of Effexor®, its popular anti-depressant drug. According to Wyeth, Effexor® XR, which is taken only once a day, uses venlafaxine hydrochloride as the active ingredient and reduces several undesirable side effects commonly associated with immediate-release Effexor®, including the incidence of nausea and vomiting. In addition to filing its ANDA, Mylan filed a "paragraph IV certification" with the FDA alleging that the three patents issued to Wyeth for Effexor® XR are invalid and would not be infringed by Mylan's manufacture, use or sale of the new drug described in its ANDA.[1]

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[1] The Federal Circuit has explained the significance of a "paragraph IV certification":

> If the ANDA contains a paragraph IV certification, and all applicable scientific and regulatory requirements have been met, approval of the ANDA 'shall be made effective immediately' unless the patent owner brings an action for infringement under 35 U.S.C.A. § 271(e)(2)(A) within forty-five days of receiving the notice required by 21 U.S.C. § 355(j)(2)(B). 21 U.S.C. § 355(j)(4)(B)(iii). The Hatch-Waxman Act further provides that, when a patent owner brings a section 271(e)(2)(A) infringement action, the FDA must suspend approval of the ANDA. Id. The suspension continues-and the FDA cannot approve the ANDA-until the earliest of three dates: (i) if the court decides that the patent is invalid or not infringed, the date of the court's decision; (ii) if the court decides that the patent has been infringed, the date that the patent expires; or (iii) subject to modification by the court, the date that

Wyeth responded to Mylan's ANDA by filing this lawsuit under the Hatch-Waxman Act, which "gives a drug patent owner the right to bring an action for infringement upon the filing of a paragraph IV certification." Bristol-Myers Squibb Co. v. Royce Laboratories, Inc., 69 F.3d 1130, 1135 (Fed. Cir. 1995) (citing 35 U.S.C. § 271(e)(2)(A)). Wyeth alleges that Mylan's proposed drug infringes on certain claims in three of its patents, specifically claims 20-25 of U.S. Patent No. 6,274,171 B1 ("the '171 patent"), claims 1, 2, 13, and 14 of U.S. Patent No. 6,403,120 B1 ("the '120 patent"), and claims 1-6 of U.S. Patent No. 6,419,958 B2 ("the '958 patent") (collectively, the "patents in suit"). These patents are related and share essentially identical specifications.[2]

All of the asserted claims of the patents in suit are "method claims," setting forth methods for using the extended release formulation of venlafaxine hydrochloride. Each claim is directed to one of two methods - either (1) "a method for providing a

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> is thirty months from the patent owner's receipt of notice of the filing of the paragraph IV certification. 21 U.S.C. § 355(j)(4)(B)(iii)(I)-(III); 35 U.S.C.A. 271(e)(4)(A).

Bristol-Myers Squibb Co. v. Royce Laboratories, Inc., 69 F.3d 1130, 1131-32 (Fed. Cir. 1995).

[2] For convenience, all citations to the specifications will be to the '171 patent unless otherwise noted.

therapeutic drug plasma concentration over a twenty four hour period with diminished incidences of nausea and emesis," see, e.g., Claim 20 of the '171 patent; or (2) "a method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride," see, e.g., Claim 24 of the '171 patent.

Following briefing and a hearing on the parties' proposed claim constructions, on May 22, 2009, the Court entered an Order that construed the contested claim terms as follows:

1. "Extended release formulation" means "a drug formulation (other than a hydrogel tablet) that releases the active ingredient at a slower rate than the immediate release formulation of the active ingredient such that the dosing frequency is once-a-day rather than the plural daily dosing for the immediate release formulation."

2. "A method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride" means "a method in which the extended release formulation is administered once in a 24-hour period, resulting in a venlafaxine blood plasma concentration that rises to a maximum value, followed

by a generally protracted decrease over the remaining period while maintaining during that 24-hour period levels of venlafaxine in blood plasma that are sufficient to provide relief from the condition being treated, thereby eliminating the multiple sharp peaks and troughs resulting from multiple daily dosing of the same total daily dose of the immediate release formulation as reflected in a graph of venlafaxine blood plasma concentration versus time."[3]

3. "Diminished incidences of nausea and emesis" means "a decrease in the number of patients suffering from nausea and vomiting compared to patients receiving the same total daily dose of an immediate release formulation that is administered at least twice a day."

4. **"**Spheroid**"** means "one or more particles that are generally shaped like a sphere, although they do not have to be perfectly round."

5. **"**Encapsulated**"** means "filled into a pharmaceutically acceptable capsule."

[3] Though the words "during the course of treatment" do not appear in the Court's Markman order addressing the limitation at issue, Wyeth correctly notes that such language was included in its proposed construction, which the Court adopted. Mylan has also used this language in its responsive filings without noting any objection, and the Court finds that the construction indeed properly includes this phrase.

6. "Administering orally to a patient in need thereof" means "a patient in need of therapeutic blood plasma levels of venlafaxine, such as a patient suffering from one or more depressive or anxiety disorders, and the patient is being treated by a formulation that is swallowed."

On June 10, 2009, Wyeth filed a motion for summary judgment in which it asserted that, based on this Court's claim construction, Mylan's proposed generic version of Effexor® XR directly infringes the asserted method claims of the patents in suit. Additionally, it contends that Mylan is liable for actively inducing infringement because, were its drug to be marketed, Mylan would advertise that the drug be used in an infringing manner and would instruct others in how to engage in an infringing use. Finally, Wyeth contends that Mylan is liable for contributory infringement because, if its proposed product is approved, Mylan would make and sell its generic drug.

Mylan also filed a motion for summary judgment, alleging that the patents in suit are invalid for lack of enablement. Based on the Court's construction of the disputed claims, Mylan asserts that Wyeth's patents are not fully enabled "commensurate with their broad scope." Specifically, Mylan contends that the patents fail to

teach and enable others to practice the full scope of the claimed invention because they teach and describe only one type of extended release formulation.

## II. SUMMARY JUDGMENT STANDARD

"Summary judgment is appropriate when there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law." Cooper Tech. Co. v. Dudas, 536 F.3d 1330, 1335 (Fed. Cir. 2008) (citing Fed. R. Civ. P. 56(c)). A court must view all facts in the light most favorable to the nonmoving party and draw all justifiable inferences in its favor. Auto. Techs. Int'l v. BMW of N. Am., Inc., 501 F.3d 1274, 1281 (Fed. Cir. 2007).

Once the moving party identifies those portions of the "the pleadings, the discovery and disclosure materials on file, and any affidavits [that] show that there is no genuine issue as to any material fact," Fed. R. Civ. P. 56(c), the burden then shifts to the non-moving party to set forth "'some evidence in the record sufficient to suggest that his view of the issue might be adopted by a reasonable factfinder.'" Glaverbel Societe Anonyme v. Northlake Marketing & Supply, Inc., 45 F.3d 1550, 1561 (Fed. Cir. 1995) (quoting Resolution Trust Corp. v. Juergens, 965 F.2d 149,

151 (7th Cir. 1992). The non-moving party, however, cannot rely on contradictions or conflicts within its own evidence. Barwick v. Celotex Corp., 736 F.2d 946, 960 (4th Cir. 1984).

## III. LEGAL ANALYSIS

### A. Wyeth's Motion for Summary Judgment on Infringement

According to Wyeth, given this Court's construction of the disputed claims, there is no genuine issue of material fact as to whether Mylan's generic form of Effexor® XR literally infringes on the asserted method claims of the patents in suit. It further contends that Mylan is liable for inducing infringement by proposing labels that would induce doctors, pharmacists and patients to use the drug in an infringing manner. Finally, Wyeth asserts that Mylan has engaged in contributory infringement by using labels that will knowingly and actively encourage others to infringe on Wyeth's patents.

#### 1. Direct Infringement of the Method Claims

> An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing.

Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996) (citations omitted).

Here, the Court has already determined the meaning and scope of the disputed claims, and thus must compare Mylan's proposed generic version of Effexor® XR to those claims. Importantly, it must compare Mylan's proposed product to the asserted method claims of the patents in suit rather than to Effexor XR®. See Zenith Labs, Inc. v. Bristol-Meyers Squibb Co., 19 F.3d 1418, 1423 (Fed. Cir. 1994).

When comparing the accused device to the claims, "the accused device infringes if it incorporates every limitation of a claim, either literally or under the doctrine of equivalents." MicroStrategy Inc. v. Business Objects, S.A., 429 F.3d 1344, 1352 (Fed. Cir. 2005) (citations omitted).[4] Thus, if "even one claim limitation is missing or not met, there is no literal infringement." Id. Moreover, where a dependant claim is allegedly infringed, the Court cannot find literal infringement unless all of the elements and limitations in both the dependent claim and the independent claim on which it relies have been infringed. See

[4] Wyeth alleges only literal infringement in this motion; thus it has waived any argument of infringement under the doctrine of equivalents. See Abbott Labs. v. Syntron Bioresearch, Inc., 334 F.3d 1343, 1355 (Fed. Cir. 2003).

Wahpeton Canvas Co., Inc. v. Frontier, Inc., 870 F.2d 1546, 1553 (Fed. Cir. 1989).

"While claim construction is a question of law, infringement is a question of fact . . . ." Byrne v. Black & Decker Corp., 235 Fed. Appx. 741, 744 (Fed. Cir. 2007) (unpublished) (citing Bai v. L & L Wings, Inc., 160 F.3d 1350, 1353 (Fed. Cir. 1998)). Where, however, "the parties do not dispute any relevant facts regarding the accused product . . ., the question of literal infringement collapses into claim construction and is amenable to summary judgment." Gen. Mills, Inc. v. Hunt-Wesson, Inc., 103 F.3d 978, 983 (Fed. Cir. 1997). Wyeth, as the patentee, bears the burden of proving infringement by a preponderance of the evidence. Laitram Corp. v. Rexnord, Inc., 939 F.2d 1533, 1535 (Fed. Cir. 1991).

Importantly, Mylan has not infringed the asserted claims by merely filing its ANDA. See Warner-Lambert, Co. v. Apotex Corp., 316 F.3d 1348, 1356-57 (Fed. Cir. 2003). Moreover, it cannot directly infringe the asserted method claims because it does not write prescriptions or treat patients. Rather, the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2)(A), permits the Court to consider whether, were Mylan to enter the market, the use of its proposed product by others would result in direct infringement of the

asserted claims. See Bristol-Myers Squibb, 69 F.3d at 1135 ("Thus, section 271(e)(2)(A) makes it possible for a patent owner to have the court determine whether, if a particular drug were put on the market, it would infringe the relevant patent."). Under this analysis, if "the court determines that the patent is not invalid and that infringement would occur . . . the patent owner is entitled to an order that FDA approval of the ANDA containing the paragraph IV certification not be effective until the patent expires." Id.

In arguing that Mylan's proposed drug directly infringes on the asserted method claims, Wyeth contends Mylan's goal has been to develop a drug that is bioequivalent to, therapeutically equivalent to, and interchangeable with, Effexor® XR, and that, in developing such a formulation, Mylan relied on the teachings of the patents in suit. It thus asserts that Mylan's proposed drug literally infringes on each element of each asserted method claim. Specifically, Wyeth contends that Mylan's generic version of Effexor:

(1) provides a "therapeutic blood [drug] plasma concentration of Venlafaxine over a twenty four hour period;"
(2) results in "diminished incidences of nausea and emesis;"

(3) is to be administered orally to patients in need of treatment;
(4) is "encapsulated;"
(5) is an "extended release formulation;"
(6) meets the pharmacokinetic limitations of the asserted claims;
(7) is a "spheriod;"
(8) results in the elimination of "troughs and peaks of drug concentration in a patient's blood plasma;" and
(9) is a "formulation containing venlafaxine hydrochloride as the active ingredient."

While acknowledging that its proposed product does meet some of these elements, Mylan asserts that genuine issues of material fact remain as to whether its drug would (1) maintain the required therapeutic blood plasma level over an entire 24 hour period, (2) eliminate "the troughs and peaks of drug concentration in a patient's blood plasma" as interpreted by this Court, (3) provide the required diminished incidences of nausea and emesis as interpreted by the Court, and (4) satisfy the required Tmax and Cmax limitations when taken as recommended on the proposed labeling.

Because the Court concludes that genuine issues of material fact exist as to whether Mylan's proposed product provides the diminished incidences of nausea and emesis, eliminates the sharp peaks and troughs, and maintains a therapeutic blood plasma level of venlafaxine as required by the asserted method claims under this

Court's construction, Wyeth has failed to establish, for purposes of summary judgment, that Mylan has infringed on the patents in suit. The Court, however, also finds that Wyeth has established that Mylan's proposed product will infringe on the claims related to Cmax and Tmax values.

**a. A genuine issue of material fact exists as to whether Mylan's proposed product provides the required diminished incidence of nausea and emesis as interpreted by this Court.**

Wyeth argues that, as a matter of law, Mylan's proposed product meets the claim limitation of diminished incidences of nausea and emesis as compared to immediate release venlafaxine. In support of its argument, Wyeth points to pooled data from three studies submitted to the FDA as part of Effexor® XR's approval process, and also to Mylan's assertion of bioequivalence, including an identical side effect profile.

In response, Mylan asserts that its evidence will undermine the reliability of the pooled data from the three studies. It claims that differences in test subjects and specific drugs administered make pooling and use of the resulting data inappropriate. It also contends that the FDA did not approve a claim of reduced nausea and emesis on the Effexor® XR label.

Only one of the three studies cited by Wyeth actually compared subjects who received the immediate and extended release forms of venlafaxine ("Study 208"). In that study, the number of subjects experiencing some nausea (the relevant value as established by the Court's claim construction) was actually identical. Another study took place among European test subjects, which Mylan's expert has testified does not necessarily reflect the side effect profile for American patients.

Mylan attempts to distinguish between bioequivalence, as required under the FDA approval process, and identical side effects. Notably, its product has not been tested on patients suffering from disorders, but only on healthy subjects. From this, Mylan asserts that side effect rates between these two populations cannot be equated accurately.

Aside from the disputed evidence related to testing, Wyeth states that its marketing experts will establish beyond debate that reduced side effects have constituted a major selling point for Effexor® XR. Wyeth offers this as circumstantial evidence that its product did in fact reduce the incidence of nausea when compared to immediate release venlafaxine, and that, as a bioequivalent drug, Mylan's product would do the same. In further support of its

argument, Wyeth's clinical expert has testified that fewer of his patients experienced nausea and emesis with Effexor® XR; however, he cannot produce any statistical evidence to support this claim.

The Court finds that further testimony at trial, especially expert testimony, would aid its understanding of the significance of Mylan's bioequivalence claims as they relate to side effects. It also requires further expert testimony regarding the reliability of the three studies and the pooled data.

In conclusion, while Wyeth's evidence of reduced incidences of nausea and emesis as shown by market success and patient experience is probative, it is not sufficiently conclusive to support a finding, as a matter of law, that Mylan's product will meet the claim limitation. Therefore, a genuine issue of material fact exists that precludes summary judgment for Wyeth on the question of Mylan's infringement of the nausea and emesis claims.

**b. A genuine issue of material fact exists as to whether Mylan's proposed product will maintain the required therapeutic blood plasma level over a 24 hour period.**

Despite efforts to limit the scope of issues for trial, the parties disagree about the interpretation of a portion of the method claims not previously addressed by the Court. Mylan argues that the phrase "therapeutic blood plasma concentration over a

twenty four hour period" requires a numerical measurement of the drug levels in the blood of a person taking extended release venlafaxine. Wyeth contends this limitation refers only to the effect arising from venlafaxine in the drug, that is relief to the patient from the condition being treated. In support, Wyeth contends that measuring blood plasma levels is not the technique used by clinicians, researchers or treating physicians to measure efficacy. Rather, doctors speak with and observe patients to determine if an effective amount of drug is being administered.

Mylan points out that Wyeth has no data establishing any specific, therapeutic blood levels of venlafaxine in patients over a twenty-four hour period, as effectuated by once-daily dosing of either Effexor® XR or Mylan's generic product, and thus cannot prove that Mylan's product will infringe on this claim. Additionally it is clear that blood plasma levels are commonly measured in research settings, if not in actual treatment situations. Such testing was apparently done for both Effexor® XR and Mylan's proposed product to generate the "plasma profiles" showing drug concentrations over time. See Wyeth Ex. 44 (Wyeth advertisement comparting plasma concentrations over twenty four hours of Effexor® and Effexor ® XR), Wyeth Ex. 31 at MYLA0002150

(Mylan bioequivalence study)("Serial blood samples . . . were collected pre-dose . . . and at 0.5, 1.0, 2.0, 4.0, 5.0, 6.0, 7.0, 8.0, 9.0, 10, 12, 14, 16, 24, 36, 48, and 72 hours post-dose.").

While Wyeth disputes the relevance of these objective measurements to the question of therapeutic effect, Mylan makes a reasonable argument that the plain language of the claim limitation requires some level of drug in the system over a twenty-four hour period. The Court, thus, finds that expert testimony on the relevance of drug plasma levels to therapeutic effect will inform a proper interpretation of the claim limitation. Additionally, the parties have provided no evidence regarding what a therapeutic level (if such a numerical value exists) would be, or whether Mylan's product would provide these levels.

For all these reasons, therefore, the Court concludes that there are genuine issues of material fact that preclude summary judgment on the issue of whether Mylan's proposed produce will maintain the required therapeutic blood plasma level over a twenty-four hour period.

**c. A genuine issue of material fact exists as to whether Mylan's proposed product will eliminate the sharp peaks and troughs associated with immediate release venlafaxine.**

The Court finds that there is a genuine issue of material fact as to whether Mylan's proposed product would eliminate the peaks and troughs of drug levels associated with immediate release venlafaxine. Mylan correctly notes that, even if its generic drug has the same dissolution profile as Effexor® XR, that facet of bioequivalence alone does not establish infringement if it cannot be shown that Effexor® XR itself meets the claim limitations. Wyeth essentially argues that Mylan's proposed product will have the same effect in the body as Effexor® XR, that Effexor® XR meets the claim limitations, and thus, Mylan's product necessarily meets (and infringes on) the claims.

Mylan challenges the second assumption in this argument, that Effexor® XR itself eliminates the sharp peaks and troughs associated with immediate release of venlafaxine. Mylan argues that such a claim requires a quantitative comparison of blood plasma levels between immediate release and extended release forms.

Because the Court must resolve whether quantifiable levels of drug concentration is an appropriate inquiry, and, if so, whether Mylan's product would provide levels corresponding to the claims of

the patents in suit, it finds that there are a genuine issues of material fact that preclude summary judgment on this issue.

**c. No genuine issue of material fact exists as to whether Mylan's proposed product will meet the Tmax and Cmax limitations of the asserted claims.**

Wyeth seeks a determination that, as a matter of law, Mylan's proposed product would meet the claim limitations of the patents in suit related to "Tmax" and "Cmax" values. Tmax refers to the time after dosing at which the concentration of drug in the system is at its peak; Cmax refers to the maximum concentration reached.

The patents in suit reference Tmax values ranging from 4 to 8 hours, or "about 6 hours." As both Mylan's proposed label and expert testimony demonstrate, the Tmax value for its generic extended release venlafaxine is 5.5 hours, putting it well within the claimed values of all the patents in suit.

Mylan argues that its own studies, conducted on both fasting and heavily fed patients, do not establish that the claimed Tmax values would be reached when taken as directed. Yet both of Mylan's studies resulted in Tmax values well within the claimed ranges. Even if the labeling (claiming a Tmax value of 5.5 hours) were inaccurate, which Mylan asserts is not the case, the two studies

confirm that its product will meet the Tmax claims when taken either with or without heavy meals.

Similarly, Mylan's label and testing establish that its product meets the claimed Cmax limitations. The label claims a Cmax value of 150ng/mL, the exact value found in the patents in suit as a maximum. The studies referenced above showed Cmax values of 117.1 ng/ml and 97.5 ng/ml, also within the claims as construed.

The Court finds that there are no genuine questions of material fact on these claims and that Mylan's product does infringe on all the Tmax and Cmax claims of the patents in suit.

**2. Inducement and Contributory Infringement**

Wyeth contends that, were Mylan to enter the market, its generic version of Effexor® XR would literally infringe on the asserted method claims of the patents in suit. It further contends that Mylan is also liable for inducing infringement and for contributory infringement. Because a showing of direct infringement is a prerequisite to liability for these additional bases for liability, however, Wyeth is not entitled to summary judgment on either of these issues. Genuine issues of material fact remain as to direct infringement, and the Court thus denies Wyeth's motion for summary judgment on these issues.

**B. Mylan's Motion for Summary Judgment on Enablement**

The Court turns next to Mylan's contention that the asserted method claims of the patents in suit are invalid because they are not fully enabled commensurate with their scope. Specifically, Mylan asserts that the patents in suit narrowly describe only a single type of extended release formulation - a coated spheroid formulation - while broadly claiming all dosage forms of the drug with the exception of hydrogel tablets.

1.

Section 112 of the Patent Act requires that, to be valid, a patent's specification must contain

> a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112, ¶ 1. These three requirements, known as the "written description requirement," the "enablement requirement" and the "best mode requirement," are independent of one another and must all be satisfied for a patent to be valid. Univ. of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 921-22 (Fed. Cir. 2004).

Whether a patent's specification has met the enablement requirement is a question of law based on underlying factual determinations. Auto. Techs. Int'l v. BMW of N. Am., Inc., 501 F.3d 1274, 1281 (Fed. Cir. 2007). "Because a patent is presumed to be valid, the evidentiary burden to show facts supporting a conclusion of invalidity is one of clear and convincing evidence." Id.

The "enablement requirement is satisfied when one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation." AK Steel Corp. v. Sollac & Ugine, 344 F.3d 1234, 1244 (Fed. Cir. 2003). Importantly, the "full scope" of the invention must be enabled; merely enabling one single embodiment of the invention does not necessarily satisfy the enablement requirement for more broadly written claims. Auto. Techs., 501 F.3d at 1285.

In two recent cases decided by the Federal Circuit, patentees argued for and obtained broad constructions of their patent claims, only to see their patents invalidated for lack of enablement. In Auto. Techs., 501 F.3d at 1279, involving a patent for a side-impact crash sensor for an automobile airbag, the district court construed a term regarding a structure corresponding to a claimed

function as including both mechanical and electronic switch assemblies. It concluded, however, that, although the specification disclosed electronic switch assemblies as a claimed structure, it failed to provide sufficient details to teach a person of ordinary skill in the art to make and use the electronic switch assemblies, and thus the patent was invalid for lack of enablement. Id. at 1280.

In affirming the district court, the Federal Circuit noted that, although it provided a general description of the electronic switch assembly, "noticeably absent [from the specification] is any discussion of the circuitry involved in the electronic side impact sensor that would provide more detail on how the sensor operates." Id. at 1283. It disagreed with the patentee's argument that the knowledge of one skilled in the art would be sufficient to supply the missing information, instead reiterating the principle that "'[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.'" Id. (quoting Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366 (Fed. Cir. 1997).

Similarly, in Sitrick v. Dreamworks, LLC, 516 F.3d 993 (Fed. Cir. 2008), a case involving technology for integrating a user's

audio signal or video image into a pre-existing video game or movie, the district court construed an asserted claim to include both video games and movies. Nevertheless, because the specification did not fully explain how the invention worked with movies, the district court invalidated the patents for lack of enablement. Id. at 999-1000. The Federal Circuit affirmed, noting that technical differences existed between how the technology would work with video games versus movies; thus, although the specification adequately taught and described the technology as it related to video games, because it was not enabled as to movies, the patent was invalid. Id. at 1000-03.

2.

In this case, the parties agree that, under the Court's construction of the term "extended release formulation," the asserted claims encompass any type of extended release dosage form, with the exception of hydrogel tablets, that achieves the objectives set forth in the method claims.[5] Mylan, however,

[5] As previously discussed, each of the method claims at issue is directed to a method of using an extended release formulation of venlafaxine hydrochloride for the purpose of either (1) providing a therapeutic drug plasma concentration over a 24-hour period with diminished incidences of nausea and emesis, or (2) eliminating the peaks and troughs of blood plasma concentration that accompany the administration of multiple daily doses of

contends that Wyeth has failed to enable the full scope of its invention because the specification teaches and describes only coated spheroid formulations, not any other type of extended release formulation. Moreover, the specification fails to identify even what other types of extended release formulations can be used to practice the method claims. The only specific reference to any other type of formulation is the hydrogel tablet, which the patents specifically disclaim.

When Wyeth filed the patents in suit, numerous types of extended release formulations existed, including hydrogel tablets, matrix systems, diffusion systems, osmotic pumps, liquid suspensions, drug coated sugar seeds, wax-filled capsules or wax-matrix capsules, multiparticulate systems, ion exchange resins, and reservoir systems. Florence Dec. Ex. E: McGinity Dec. 5:6-9:6; Ex. J: Van Buskirk Dec. ¶ 17. Mylan contends, however, that, when the patents were filed, only one of these formulations, osmotic pump systems, had been utilized with venlafaxine hydrochloride. Florence Dec. Ex. G: the Alza patent. It further contends that Wyeth itself had attempted to make extended release formulations of venlafaxine using hydrogel tablets and Gelucire® wax capsules, but

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venlafaxine hydrochloride.

had failed to succeed with either. Florence Dec., Ex. J: Van Buskirk Dec. ¶¶ 32-33; Ex. I: Wyeth Development Report. While this Court's construction of "extended release formulation" explicitly excludes extended release formulations using hydrogel tablets, all other types of formulations are encompassed, including Gelucire® wax capsules.

Mylan further contends that, at the time Wyeth filed the patents in suit, a person of ordinary skill in the art would not have had experience in designing the full range of preexisting extended release drug forms. It admits that, at the time of filing, the preexisting forms and methods for making them would have been taught at pharmacy schools, and thus a person of ordinary skill the art would have been familiar with the range of forms. Nonetheless, through the testimony of its expert, Dr. Van Buskirk, Mylan asserts that such a person would not have had actual hands-on experience designing and making all of the various forms. Florence Dec Ex. J: Van Buskirk Dec. ¶ 18. Dr. Van Buskirk also testified that knowledge of how to make one type of dosage form does not necessarily translate to other forms. Id. Thus, Mylan contends, that a person of ordinary skill in the art would have been required

to engage in undue experimentation to utilize all the dosage forms claimed by the patents in suit.

Finally, Mylan argues that each type of extended release dosage form has unique properties and challenges that would necessarily require extensive experimentation in order to achieve the venlafaxine release profile disclosed in the asserted method claims. According to Dr. Van Buskirk,

> [A]lthough[] there may be some predictability of chemical behavior of certain classes of drugs and chemical compounds, the development process of a successful drug formulation is iterative and often requires years of extensive trial-and-error experimentation in the development of a particular type of extended release dosage form. There are also numerous variables that affect the development process, such as the component compatibility, combination of rate-controlling excipients, and ratio of the active and inactive ingredients, and the desired pharmacokinetic characteristics of the active drug substance. Each of these characteristics changes with the type of dosage form utilized.

Florence Dec. at Ex. J: Van Buskirk Dec. ¶ 21.

Mylan points to the extensive trial and error experimentation Wyeth itself undertook to meet the release profile using an extruded spheroids formulation. Indeed, in the specification's "Detailed Description of the Invention," Wyeth acknowledged:

> Numerous spheroid formulations were prepared using different grades of microcrystalline cellulose and hydroxypropylmethylcellulose, different ratios of

> venlafaxine hydrochloride and filler, different binders such as polyvinylpyrrolidone, methylcellulose, water, and polyethylene glycol of different molecular weight ranges in order to find a formulation which would provide a suitable granulation mix which could be extruded properly. In the extrusion process, heat buildup occurred which dried out the extrudate so much that it was difficult to convert the extruded cylinders into spheroids.

'171 patent, Col. 5:1-11. According to Mylan, this passage underscores that significant experimentation was necessary before Wyeth was able to develop this particular dosage form, and that similar experimentation would have been necessary to develop other types of dosage forms.

3.

Wyeth does not dispute that its specification describes only one type of extended release formulation. But it argues vigorously that the novel aspects of its asserted method claims are the discoveries that "blood plasma levels having the claimed pharmacokinetic characteristics are feasible and provide twenty four hour therapeutic efficacy and improved tolerability," and not the use of any particular extended release formulation. Wyeth's Resp. Br., p. 8. Because Auto. Techs., 501 F.3d at 1283, requires that the specification "must supply the novel aspects of an invention in order to constitute adequate enablement," Wyeth

contends that the extended release drug formulations, which are not novel, need not be described. (Emphasis added).

Wyeth further contends that Federal Circuit precedent permits patentees to rely on the knowledge of one of ordinary skill in the art to establish enablement as to aspects of the invention that are not novel. It points out that "a patent need not teach, and preferably omits, what is well known in the art." Hybritch Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384 (Fed. Cir. 1986). Wyeth further argues that, unlike the unenabled claim in Auto. Techs., extended release formulations are not a new field, and no specific type of extended release formulation is required to practice the claimed methods in these patents. Thus, because one of ordinary skill in the art at the time the patents were issued would have had a general understanding of different extended release formulations and of the various methods of making them, Wyeth asserts it was not required to explicitly describe that aspect of the invention.

Wyeth also notes that the specification in this case plainly stated that the "encapsulated formulations of this invention may be produced . . . by techniques understood in the art." '171 patent, 5:14-17. It points out that the 1995 addition of Remington: The

Science and Practice of Pharmacy, a pharmaceutical textbook available at the time the patents in suit were filed, explains that drug-containing spheroids can be formed through multiple techniques, such as an extrusion/spheronization process, or through applying a drug-containing coating to a crystal or nonpareil seed. Wyeth Ex. 13, McGinity Dec. ¶ 22. Wyeth's expert, Dr. James McGinity, has explained that, under either method, an extended-release coating can subsequently be applied. Id. He has further stated that "the method of manufacture of a spheroid would be considered by one of ordinary skill in the art as totally irrelevant to how they work in delivering the drug to the body" because the extended release coating that is applied after the drug-containing spheroid is formed controls the release of the drug. Id. at ¶ 23.

Finally, Wyeth contends that Table 1 in the specification of the patents in suit is a bench test screening tool that enables those skilled in the art to use existing technology to find other formulations to practice Wyeth's method inventions. Mylan disputes Table 1's utility, however, arguing that it merely provides dissolution goals and applies only to extended drug formulations in the form of coated spheroids. It points out that the specification

teaches that, where the desired dissolution rate is not met, the amount of coating should be adjusted. See '171 patent, Col 6:42-64. Dr. Van Buskirk contends that the specification fails to provide any guidance whatsoever to a person of ordinary skill in the art attempting to achieve the target dissolution profile in an extended release formulation that does not utilize a coating to extend the drug release. Florence Dec. Ex. J: Van Buskirk Dec. ¶ 25.

4.

To aid a court in determining whether claims such as these have been sufficiently enabled to avoid undue experimentation, the Federal Circuit has provided eight factors. Called the "Wands factors," these include:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

Indeed, the Court need only consider several of the Wands factors to conclude that there are material factual disputes as to whether a person of ordinary skill in the art could have replicated

the results of the asserted method claims without undue experimentation. See Wands, 858 F.2d at 737.

In considering the first Wands factor for example, a genuine issue of material fact exists as to the amount of experimentation a person of ordinary skill in the art at the time would have had to undertake to achieve the extended release formulation in a form other than a coated spheroid. As Mylan points out, the patents make clear that significant experimentation was required to achieve the coated spheroids that are the preferred embodiment, see '171 patent, Col. 5:1-11, thus implying that other types of dosage forms would have required similar experimentation. Wyeth's expert, Dr. McGinity, nevertheless has stated that only routine experimentation would have been necessary for one of ordinary skill in the art to develop alternative formulations that would meet the dissolution goals. Wyeth Ex. 13, ¶ 22. Dr. Van Buskirk emphatically rejects this conclusion, stating that such development would have involved "extensive trial and error testing." Florence Dec. Ex. J: Van Buskirk Dec. ¶ 27. Clearly, whether the required experimentation would have been merely routine is a disputed issue. See Wands, 858 F.2d at 737.

Regarding the sixth Wands factor, the parties vigorously dispute whether one of ordinary skill in the art at the time the patents were issued would have been readily able to develop extended release formulations, other than coated spheroids, that met the requirements of the asserted claims without being given specific instructions as to how to develop those formulations. Wyeth has presented evidence that a pharmaceutical textbook from the period indicated that one of ordinary skill in the art would have understood how to develop extended release formulations using spheroids developed through either the extrusion and spheronization process, or by coating nonpareil seeds. See Wyeth Ex. 13, McGinity Dec. ¶ 22. In addition, its expert, Dr. McGinity, has stated that, in his opinion, ". . . the relative skill of those in the art with respect to making a wide variety of extended release drug formulations in March 1996 was relatively high . . . ." Id. at ¶ 32.

Mylan, on the other hand, has presented evidence that the osmotic pump system was the only extended release formulation to have been utilized in connection with venlafaxine hydrochloride prior to the patents in suit. Florence Dec., Ex. G. Mylan's evidence, moreover, indicates that Wyeth attempted to utilize other

extended release formulations, such as hydrogel tablets and Gelucire® wax capsules, but failed to succeed with either, thus leading to the inference that one of ordinary skill in the art could not necessarily have easily adapted other types of extended release formulations to venlafaxine hydrochloride and achieved the targeted dissolution rates. See Florence Dec., Ex. J: Van Buskirk Dec. ¶¶ 32-33; Ex. I: Wyeth Development Report.

When determining whether "undue experimentation" would have been required to enable a particular aspect of Wyeth's patent claims, the Court is to reach its decision "by weighing many factual considerations." Wands, 858 F.2d at 737. Given that genuine questions of fact remain as to at least two of the Wands factors, the Court need not consider any remaining factors at this time. Having determined that genuine questions of material fact are in dispute as to the issue of enablement, the Court **DENIES** Mylan's motion for summary judgment on this issue.

**B. Wyeth's Motion for Summary Judgment on Inventorship**

Wyeth argues that the patents in suit are not invalid for failure to name one or more inventors. Mylan has claimed that two individuals, Dow Chemical sales representative, Paul Sheskey, and

Wyeth employee, Dr. Wendy Dulin, should have been named as inventors of the patents in suit.

> The inventors as named in an issued patent are presumed to be correct. Thus, a party alleging non-joinder must meet the heavy burden of proving its case by clear and convincing evidence.

Nartron Corp. v. Schukra U.S.A. Inc., 558 F.3d 1352, 1356 (Fed. Cir. 2009)(citations omitted).

Nartron, however, compels a finding that Paul Sheskey was not an inventor of the patents in suit. In Nartron, the Federal Circuit held that a person who merely provides information within the prior art, without knowledge of the invention as a whole, could not be a co-inventor. Here, Sheskey merely provided Deborah Sherman, a Wyeth employee and named inventor, with information about a Dow product that would meet the specifications she indicated she required. He did not know the drug on which Sherman was working. Moreover, Sheskey disclaims any ownership interest in the patent.

Dr. Wendy Dulin, however, had more than a passing involvement in Wyeth's development of venlafaxine extended release formulations. She worked on lower dosage versions of the drug and was able to create a version that did not require the chemical HPMC (coincidentally, the same chemical Sheskey supplied). While Mylan argues that this work was sufficiently creative to qualify Dr.

Dulin as an inventor, Wyeth points out that her work was merely the product of prior experimentation and development at Wyeth, and that the inventions were fully conceived before Dr. Dulin began her work.

While some factual questions may remain regarding this issue, the Court is satisfied that they are not material and it need not resolve them. Failure to name an inventor is not grounds for invalidating a patent when such a name can be added under 35 U.S.C. § 256. Under this provision, an inventor can be added to a patent unless "deceptive intention" on the part of the patent holder can be shown by clear and convincing evidence. C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1353 (Fed. Cir. 1998).

Mylan's argument that Wyeth's deceptive intention in this case may be inferred from its past additions of inventors to the patents and its failure to name Dr. Dulin fails. The contention that Wyeth's failure to name Dr. Dulin was part of a scheme to avoid potential liability to Sheskey and Dow Chemical lacks any evidentiary support. Even if Dr. Dulin were an inventor (and she, like Sheskey, disclaims any such interest), Mylan cannot show by clear and convincing evidence that Wyeth harbored any deceptive intent in its failure to name proper inventors. Thus, because the

patents would not be invalid in any event, the Court grants Wyeth's motion for summary judgment on this issue.

## IV. CONCLUSION

For the reasons discussed, the Court **DENIES** Wyeth's motion regarding infringement (dkt. no. 160), **DENIES** Mylan's motion regarding enablement (dkt. no. 162), and **GRANTS** Wyeth's motion regarding inventorship (dkt. no. 178).

It is so **ORDERED**.

The Clerk is directed to transmit copies of this Order to counsel of record.

DATED: October 14, 2009.

/s/ Irene M. Keeley
IRENE M. KEELEY
UNITED STATES DISTRICT JUDGE